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09/750,779	01/02/2001	Wei-ping Li	12013/55202	7468

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[REDACTED] EXAMINER

NGUYEN, DAVE TRONG

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Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. <b>09/750,779</b>	Applicant(s) <b>Li</b>	
	Examiner <b>Dave Nguyen</b>	Art Unit <b>1632</b>	
<b>-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --</b>			
<b>Period for Reply</b> A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE <u>3</u> MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.			
- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).			
<b>Status</b>			
1) <input checked="" type="checkbox"/> Responsive to communication(s) filed on <u>Sep 25, 2002</u>			
2a) <input type="checkbox"/> This action is <b>FINAL</b> .      2b) <input checked="" type="checkbox"/> This action is non-final.			
3) <input type="checkbox"/> Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11; 453 O.G. 213.			
<b>Disposition of Claims</b>			
4) <input checked="" type="checkbox"/> Claim(s) <u>1-46</u> is/are pending in the application.			
4a) Of the above, claim(s) <u>7 and 8</u> is/are withdrawn from consideration.			
5) <input type="checkbox"/> Claim(s) _____ is/are allowed.			
6) <input checked="" type="checkbox"/> Claim(s) <u>1, 4-6, 9, 10, 15, 19, 24, and 28-46</u> is/are rejected.			
7) <input checked="" type="checkbox"/> Claim(s) <u>2, 3, 11-14, 16-18, 20-23, and 25-27</u> is/are objected to.			
8) <input type="checkbox"/> Claims _____ are subject to restriction and/or election requirement.			
<b>Application Papers</b>			
9) <input type="checkbox"/> The specification is objected to by the Examiner.			
10) <input checked="" type="checkbox"/> The drawing(s) filed on <u>11201</u> is/are a) <input type="checkbox"/> accepted or b) <input checked="" type="checkbox"/> objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).			
11) <input type="checkbox"/> The proposed drawing correction filed on _____ is: a) <input type="checkbox"/> approved b) <input type="checkbox"/> disapproved by the Examiner. If approved, corrected drawings are required in reply to this Office action.			
12) <input type="checkbox"/> The oath or declaration is objected to by the Examiner.			
<b>Priority under 35 U.S.C. §§ 119 and 120</b>			
13) <input type="checkbox"/> Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) <input type="checkbox"/> All b) <input type="checkbox"/> Some* c) <input type="checkbox"/> None of: 1. <input type="checkbox"/> Certified copies of the priority documents have been received. 2. <input type="checkbox"/> Certified copies of the priority documents have been received in Application No. _____. 3. <input type="checkbox"/> Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). *See the attached detailed Office action for a list of the certified copies not received.			
14) <input checked="" type="checkbox"/> Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e). a) <input type="checkbox"/> The translation of the foreign language provisional application has been received.			
15) <input type="checkbox"/> Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.			
<b>Attachment(s)</b>			
1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)		4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____	
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)		5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)	
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____		6) <input type="checkbox"/> Other: _____	

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Applicant's election without traverse the invention directed to a medical device comprising a therapeutic DNA encoding an angiogenic protein, and gene therapy methods of employing the elected medical device, in the response filed September 26, 2002 is acknowledged.

Applicant's election without traverse of the species of chitosan, the species of a balloon catheter, and the species of a heart in the response filed September 26, 2002 is also acknowledged.

Upon a further consideration, the group restriction has been vacated by the examiner. In addition, a search of prior art readable on gelatin and chitosan was not undue, and thus the species restriction with respect to the two species has been withdrawn by the examiner. However, the species restriction as to other claimed species is maintained for the reasons of record.

Claims 2, 3, and 10-46 are free of the prior art of record because the prior art of record does not teach or suggest the use of alternate layers of a cationic polyelectrolyte carrier as outer layers and at least one inner layer of at least one negatively charged therapeutic agent in a coated medical device. As such, the species restriction as to these claims have been withdrawn by the examiner.

Claims 7 and 8 have been withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected species.

Claims 6, 15, 24, 33 and 43 are objected because the "vascular cell growth promoters" should be written as -- vascular cell growth promoters --.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 6, 10, 15, 19, 24, 28, 33, 38, and 43 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably

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convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

With respect to the presently pending claims, drawn specifically to the agents as listed in claims 6, 15, 24, 33 and 43, the specification only provides sufficient description of anti-thrombogenic proteins (heparin, heparin derivatives, urokinase, and PPACK), antioxidant compounds (probucol and retinoic acid), angiogenic proteins, agents which block smooth muscle cell proliferation, anti-inflammatory agents, calcium entry blockers, antineoplastic/antiproliferative/anti-mitotic compounds, anti-microbial compounds, anesthetic agents, nitric oxide donors, anti-coagulants, vascular cell growth promoting proteins, vascular cell growth protein inhibitors, vascular cell growth antibody inhibitor, cholesterol lowering drugs, vasodilating drugs, proteins that protect against cell death, cell cycle CDK protein inhibitor, anti-restenosis proteins, agents for treating malignancies, bone morphogenic protein, and polynucleotides encoding any of the above named proteins. However, the claims as written embrace an enormous number of anti-thrombogenic agents other than anti-thrombogenic proteins, angiogenic agents other than angiogenic proteins, vascular cell growth promoting agents other than growth factors, vascular cell growth inhibitors other than antibodies or anti-growth factor proteins, agents other than proteins that protect against cell death, cell cycle inhibitors other than cell cycle CDK protein inhibitors, anti-restenosis agents other than anti-restenosis proteins, and of polynucleotides encoding any of the agents as claimed including those compounds (small molecular weight compounds or drugs) that is not known by any prior art to be encoded by a polynucleotide.

It is apparent that on the basis of applicant's disclosure, an adequate written description of the invention defined by the claims requires more than a mere statement that it is part of the invention and reference to potential methods and/or assays and/or formula containing unspecified molecular structures of molecules that are essential for the making the genus of one or more negatively charged therapeutic agents as claimed; what is required is the knowledge in the prior art and/or a description as to the availability of a representative number of species of biochemical or molecular structures of one or more negatively charged therapeutic agents which are employed in the context of implantation of therapeutic molecules by medical delivery devices that must exhibit the disclosed biological functions as contemplated by the as-filed specification.

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It is not sufficient to support the present claimed invention directed to a formula containing no chemical structure but rather just functional effect of the drugs and/or DNA encoding "such agents" because the disclosure of no more than what were indicated on pages 9 and 10 of the specification, as in the instant case, is simply a wish to know the identity of any and/or all other agents and/or DNA having the biological functions as contemplated by the specification and the claims. The claimed invention as a whole is not adequately described if the claims require essential or critical elements which are not adequately described in the specification and which is not conventional in the art as of applicants effective filing date. Claiming unspecified molecular structures of other agents and/or DNA encoding "such agents" that must possess the biological properties as contemplated by applicant's disclosure without defining what means will do so is not in compliance with the written description requirement. Rather, it is an attempt to preempt the future before it has arrived. (See *Fiers v. Revel*, 25 USPQ2d 1601 (CA FC 1993) and *Regents of the Univ. Calif. v. Eli Lilly & Co.*, 43 USPQ2d 1398 (CA FC, 1997)). Possession may be shown by actual reduction to practice, clear depiction of the invention in a detailed drawing, or by describing the invention with sufficient relevant identifying characteristics such that a person skilled in the art would recognize that the inventor had possession of the claimed invention. Pfaff v. Wells Electronics, Inc., 48 USPQ2d 1641, 1646 (1998). The skilled artisan cannot envision the detailed structure of a genus of the claimed and recited agents that must exhibit the contemplated biological functions, and therefore, conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the structures and/or methods disclosed in the as-filed specification. Thus, In view of the reasons set forth above, one skilled in the art at the time the invention was made would not have recognized that applicant was in possession of the claimed invention as presently claimed.

Claims 1, 6, 10, 15, 19, 24, 28, 33, 36, 38, and 43 are rejected under 35 U.S.C. 112, first paragraph, because the specification is enabling only for claims limited to:

A medical device as claimed in linking claims 1, 10, 15, 28 and 38, wherein at least one of the one or more negatively charged therapeutic agent comprises at least one agent selected from the group

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consisting of anti-thrombogenic proteins, antioxidant compounds, angiogenic proteins, agents which block smooth muscle cell proliferation, anti-inflammatory agents, calcium entry blockers, antineoplastic/antiproliferative/anti-mitotic compounds, anti-microbial compounds, anesthetic agents, nitric oxide donors, anti-coagulants, vascular cell growth promoting proteins, vascular cell growth protein inhibitors, vascular cell growth antibody inhibitor, cholesterol lowering drugs, vasodilating drugs, proteins that protect against cell death, cell cycle CDK protein inhibitor, anti-restenosis proteins, agents for treating malignancies, bone morphogenic protein, and polynucleotides encoding any of said proteins or protein inhibitors.

Claims 28-46, readable on a gene therapy method for treating or reducing the occurrence or severity of a clinical disease or condition by an implantation of the claimed medical device at any location, e.g., *in vitro*, are also rejected under 35 U.S.C. 112, first paragraph, because the specification is enabling only for claims limited to:

A method delivering a therapeutic agent to a mammal, the method comprising implanting a medical device comprising the coating as recited in claim 28 at a desired location or tissue in a mammal, wherein the coating comprises a therapeutic agent;

A method delivering a DNA encoding a protein to a mammal, the method comprising implanting a medical device comprising the coating as recited in claim 38 at a desired location or tissue in a mammal, wherein the coating comprises a polynucleotide encoding a protein; and

A method delivering a DNA encoding a therapeutic protein to a mammal, the method comprising implanting a medical device comprising the coating as recited in claim 38 at a desired location or tissue in a mammal, wherein the coating comprises a polynucleotide encoding a protein selected from the group consisting of anti-thrombogenic proteins, angiogenic proteins, vascular cell growth promoting proteins, vascular cell growth protein inhibitors, proteins that protect against cell death, cell cycle CDK protein inhibitor, anti-restenosis proteins, and bone morphogenic protein.

The specification does not reasonably provide enablement for the presently pending claims encompassing any other combination of therapeutic agents and/or DNA encoding such agents. The

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specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in In re Wands, 858 F.2d 731, 8USPQ2d 1400 (Fed. Cir. 1988). They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

Specifically, since the claimed invention is not supported by a sufficient written description (for possessing of the genus of agents and/or polynucleotides encoding "such agents" for use in an implantable or insertable delivery device as recited in the claims, particularly in view of the reasons set forth above, one skilled in the art would not know how to use and make the claimed invention so that it would operate as intended.

In addition, the claims as written do not necessarily limit the "location" to a desired location or target tissue in a mammal. However, the specification only teaches that in order to employ the claimed medical device within applicant's framework of the invention, it is necessary to implant the claimed medical device to a desired target tissue in a mammal. As such, it is not apparent how one skilled in the art practices the full breadth of the claimed methods on the basis of applicant's disclosure.

With respect to claims readable on a method of gene therapy to treat or reduce the occurrence or severity of a clinical disease or condition in any animal, Applicant's claimed invention encompasses gene therapy products so as to prevent the occurrence of a disease or condition, or to produce a therapeutic effect in any subject having any disease by using a medical device comprising any therapeutic DNA including antisense, nucleic acids, and vectors comprising any therapeutic gene, including those that are yet to be discovered. The specification indicates that any disease including vascular diseases, non-vascular can be therapeutically treated by using the claimed method and/or pharmaceutical compositions.

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Other than a sufficient enablement of direct administration of an anti-proliferative gene to inhibit restenosis or the growth of tumor cells in a mammal, and of a DNA coding for an angiogenic factor to induce the growth of blood vessels at a site of the local delivery of the DNA, as indicated in the specification and state of the prior art of record (Isner, US Pat No. 5,652,225, for example), it is not apparent as to how one skilled in the art determines, without undue experimentation, as to which of other DNA as embraced by the claims would exhibit a therapeutic effect in the treatment of a disorder, particularly on the basis of applicant's disclosure, and given the unpredictability of nucleic acid therapy methods at the time the invention was made (Anderson *et al.*, Nature, Vol. 392, 25-30, April 1998). With respect to the use of DNA coding for antisense, ribozymes, triplex oligonucleotides, to treat a tissue *in vivo* therapeutically, the application does not demonstrate a therapeutic effect in any subject using any of the disclosed DNA as claimed. There is no evidence for an affect on any disease symptom using any of applicant's therapeutic nucleic acid. Major considerations for any gene transfer or gene therapy protocol involve issues such as amount of DNA constructs to be administered, what amount is considered to be therapeutically effective for all of the claimed nucleic acid molecules, the route and time course of administration, the sites of administration, successful uptake of the claimed DNA at the target site, expression of the DNA at the target site in amounts of effecting the treatment in a treated subject (Anderson, Nature, Vol. 392, 25-30, April 1998; Rosenberg, Science, Vol. 287, page 1751, 2000). More specifically, Anderson teaches that results in one particular animal model have not always reflected what happens in another animal model (page 28, column 1, first paragraph), that gene therapy is a powerful new technology that still requires several years before it will make a noticeable impact on the treatment of disease, and that several major deficiencies still exist including poor delivery systems, both viral and non-viral, and poor gene expression after genes are delivered (page 30, column 1, last paragraph). Anderson further teaches that the reason for the low efficiency of gene transfer and expression in human patients is that we still lack a basis understanding of how vectors should be constructed, what regulatory sequences are appropriated for which cell types. Verma *et al.* (Nature, Vol. 389, 18, September 1997, pages 239-242) also states that "the Achilles heel of gene therapy is gene delivery", that "thus far, the problem has been an inability to deliver genes efficiently

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and to obtain sustained expression", that gene delivery methods using non-viral vectors "suffer from poor efficiency of delivery and transient expression of the gene", and that "although there are reagents that increase the efficiency of delivery, transient expression of the transgene is a conceptual hurdle that needs to be addressed" (page 239, column 3, first paragraph). Furthermore, Verma *et al.* indicate that factors including the nature of the diseases and/or disorders, the nature of a DNA and/or target tissue, and a delivery system and/or amounts of the DNA complexes employed in the delivery system that would generate a therapeutic effect *in vivo* must be considered for any gene therapy method to be successful (page 238, columns 1 and 2). With respect to antisense therapy, Branch (TIBS 23, pp. 45-50, 1998) even in 19998, antisense and ribozyme therapy remains unpredictable (entire document). The specification does not provide sufficient guidance and/or factual evidence demonstrating a reasonable correlation between the disclosure and the subject matter being sought in the claims. Thus, it is not apparent as to how one skilled in the art reasonably extrapolates, without any undue experimentation, from a therapeutic effect generated by direct injection of DNA coding for an angiogenic factor, as demonstrated in the prior art of record, to any and/or all pharmaceutical products as recited in the presently pending claims, particularly given the unpredictability of gene therapy and/or the doubts expressed in the art of record. Note that the essential attributes and/or criteria of the claimed DNA gene therapy compositions as claimed, e.g., routes of administrations, dosages, and/or specific structures of antisense and/or ribozymes, and/or therapeutic DNA, that exhibit a therapeutic effect, are not sufficiently described in the as-filed specification so as to overcome the doubts expressed in the art of record. Note that the issue is not that the specification and the prior art of record does not reasonably provide an enablement of a method of using the claimed medical device to provide the proteins as disclosed and supported by the as-filed specification to any mammal, but is rather that at the time the invention was made, the use of the claimed medical device to treat or reduce the occurrence or severity of any clinical disease or condition in any animal is neither routine nor reasonably predictable at the time the invention was made. Thus, the specification is not enabling under 35 U.S.C. 112, first paragraph, for any and/or all therapeutic nucleic acid constructs within the context of treatment of

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any disease in any subject, particularly on the basis of applicant's disclosure and the reasons stated in the art of record.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 28-38, and 46 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Base claim 28 and claims dependent there from are indefinite in the recitation of "near the target location" because the "near" is a relative terminology and does not exactly define the intended metes and bounds of the "near the target location". Deletion of the "near" is suggested.

Claims 37 and 46 in the recitation of "urethra malignant growth, or benign growth" are indefinite because it is not apparent how a growth of urethra can be a structural location or tissue at which the claimed medical device can be implanted. In addition, it is not apparent as to what are exactly the metes and bounds of "benign growth". It is not clear as to what would constitute the "benign growth". Clarification is requested.

Because of the recitation of "optionally" in claim 1, the following rejections are applicable.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the

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effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 1, drawn to a generic medical device comprising a gelatin coated layer onto which another layer of negatively charged therapeutic agent is bound, is rejected under 35 USC 102(e) as being anticipated by Shi *et al.* (US Pat No. 6,044,943).

Shi teaches that a medical device already having a coating further comprising a protein (gelatin, for example) coated layer onto which another layer of genetic materials encoding a therapeutic protein is adsorbed (column 3). The further coating of crosslinked proteins onto the medical device is to provide biocompatibility and biodegradability and reduce toxicity and/or side effects (column 1 bridging column 2).

Absent evidence to the contrary, the medical device of Shi has all of the properties cited in claim.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that

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was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 4-6, and 9, readable on just a medical device comprising essentially of just an inner layer of chitosan based polymeric coating and an outer layer of adenoviral vectors encoding an angiogenic protein, are rejected under 35 USC 103(a) as being unpatentable over Haimovich (US Pat No. 5,578,073 taken with Shi (US Pat No. 6,004,943) and Neufeld (US Pat No. 6,013,780).

Haimovich teaches a catheter as a medical device comprising a chitosan based polymeric coating in order to provide a thromboresistance surface, and a biologically active material, which can be bound onto the surface of activated chitosan in the coating layer (entire disclosure, particularly column 3).

Haimovich does not teach the use of a chitosan-based catheter onto which a layer of adenoviral vectors encoding an angiogenic protein is bound.

However, at the time the invention was made, Shi teaches that a medical device already having a coating further comprising a protein (gelatin, for example) coated layer onto which another layer of genetic materials is adsorbed (column 3). The further coating of crosslinked proteins onto the medical device is to provide biocompatibility and biodegradability and reduce toxicity and/or side effects (column 1 bridging column 2).

In addition, Neufeld teaches that a gene therapy method of providing a VEGF angiogenic protein to an ischemic region of the heart in a mammal comprising employing a coated balloon catheter onto which adenoviral vectors encoding a VEGF protein are carried (entire disclosure, columns 5, 20-22).

It would have been obvious for one of ordinary skill in the art to have coated the chitosan based medical device of Haimovich with a protein (gelatin, for example) coated layer onto which another layer of genetic materials is adsorbed (column 3). One would have been motivated to do so because the further coating of crosslinked proteins onto the medical device is to provide biocompatibility and biodegradability and reduce toxicity and/or side effects. In addition, one would have been motivated to have employed the combinations of layers and/or coatings as taught in the combined Haimovich and Shi on the balloon

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catheter and further employ the multiplayer coated balloon catheter to implant adenoviral vectors encoding a VEGF at an ischemic region of the heart in a mammal. One of ordinary skill in the art would have been motivated to do so because teaches the applications of chitosan and/or gelatin based coatings on the surface of any medical device provide biocompatibility and biodegradability and reduce toxicity and/or side effects of thrombogenesis, and because Neufeld teaches that coated balloon catheters are effective medical device to deliver adenoviral vectors encoding VEGF to promote angiogenesis at an ischemic region of the heart in a mammal.

Thus, the claimed invention as a whole was *prima facie* obvious.

Claims 2, 3, 11-14, 16-18, 20-23, and 25-27 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications regarding the formalities should be directed to Patent Analyst Tiffany Tabb, whose telephone number is **(703) 605-1238**.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner *Dave Nguyen* whose telephone number is **(703) 305-2024**.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, *Deborah Reynolds*, may be reached at **(703) 305-4051**.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is **(703) 305-7401**.

Any inquiry of a general nature or relating to the status of this application should be directed to the *Group receptionist* whose telephone number is **(703) 308-0196**.

Dave Trong Nguyen  
Primary Examiner  
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DAVE T. NGUYEN  
PRIMARY EXAMINER